Study Title: Adaptation and Feasibility Testing of a Fatigue Intervention in Adults with TBI
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Background

Many who experience disabilities related to TBI describe Post Traumatic Brain Injury Fatigue (PTBIF) as their most challenging symptom[1], significantly impacting their daily functioning, social participation, and overall psychological health and well-being for many years, and sometimes for a lifetime, post injury.[2,3] Beyond its impact, PTBIF is challenging to manage, as it is multidimensional and not always visibly detectable. It cannot be quantified by blood samples or other tests, though it is persistent, profoundly debilitating, and occurs in 43% to 73% of persons with TBI (pwTBI).[4,5] PTBIF is associated with a variety of cognitive symptoms (attention and processing), emotional problems (depression and anxiety), and pain, making it difficult to safely return to duty and/or other daily activities.[6-8] Despite its wide prevalence and debilitating effects, PTBIF is often overlooked and therefore significantly under-treated in TBI rehabilitation.[9,10]

Recent research suggests that a cognitive behavioral approach is the most effective intervention for managing fatigue[11,12], as this approach provides an interactive program that moves beyond traditional didactic education by developing the skills necessary to self-manage fatigue. However, CBT approaches to fatigue have been validated only in patients with MS and cancer. Despite a similar experience of fatigue burden to patients with MS and cancer[13], only recently have cognitive behavioral approaches specifically designed to address fatigue after TBI been conceived. These interventions vary extensively regarding theoretical basis, intervention platform, frequency, duration, and delivery methods and are in the early stages of research.[11] While many of these pilot studies suggest promising results[13], the "active ingredients" in these approaches have not been defined nor has their effectiveness been determined.[13] Additionally, access to cognitive behavioral services is limited by structural barriers, including limited financial resources, unavailable providers, lack of transportation, and inconvenience.[14] Persons with TBI experience *additional barriers* to accessing mental health and other services due to having more limited transportation options, being less likely to have healthcare coverage, and an even greater shortage of specialized providers.[15,16] These barriers are further magnified among racial/ethnic minoritized groups.[17-19] In a mental health survey study of 1023 U.S. Veterans, more than half screened positive for likely mental health disorders, yet only a third received mental health care within the past year (only 1 in 50 in the past month).[20] Thus, there is a **critical need** to adapt and optimize evidence-based mental health and cognitive interventions to be more available, accessible, and efficient for community-dwelling TBI survivors.

Proposed solution: FACETS(Fatigue: Applying Cognitive Behavioral and Energy Effectiveness Techniques to LifeStyle), an accessible evidence-based cognitive behavioral intervention for fatigue, could address this critical need, as it can be delivered remotely, is adaptable, and teaches the requisite skills for effective self-management that empowers participants to independently address fatigue-related needs, regardless of their nature, over time. Developed in the United Kingdom in 2009 by Research Psychologist, Sarah Thomas PhD (proposed project Co-I), FACETS was designed based on a model of good practice in chronic fatigue syndrome to address chronic fatigue in individuals with Multiple Sclerosis.[21] FACETS content is based on current theories about causes and treatment of MS-fatigue, as well as insights from individuals with MS and an Intervention Development Advisory Group comprised of health professionals with relevant expertise.

Our team has adapted FACETS to meet the needs of civilians and Service members with PTBIF using a robust intervention adaptation framework, ADAPT Guidance, eliminating the need to develop an intervention *de novo*.[22-24] We selected the ADAPT Guidance[23,25] framework (**Figure 1**), as it is designed to achieve good fit between intervention and context through a careful and systematic 4-step adaptation process that emphasizes inclusion of a diverse stakeholder team throughout the process. By adapting FACETS to FACETS-TBI through a collaborative team-based process, we were able to expedite the development of a patient-centered cognitive

behavioral intervention to meet the needs of civilians and Service members with PTBIF. The next step is to test FACETS-TBI in pw-TBI who experience fatigue.

Objectives/specific aims

Objective: The purpose of this project is to pilot test the remote intervention, FACETS-TBI, in pwTBI who experience fatigue**.**

Specific Aim 1) Test an attention control protocol designed to control for the non-specific effects of the FACETS program (dose, attention). We hypothesize that: *Hypothesis1a*: The number of participants retained, duration of sessions, number of sessions completed/reason for non-completion, participant understanding of content, and level of participation in the intervention will be similar in participants who engage in FACETS-TBI and participants who receive Attention Control. *Hypothesis 1b:* Participants in the Attention Control group will demonstrate similar acceptability of the intervention as participants who receive FACETS-TBI, measured by the Client Satisfaction Questionnaire. *Hypothesi1c*: FACETS-TBI and Attention Control protocols will be delivered with high fidelity and successfully prevent contamination (conceptual and integrity) of either intervention, as measured by an intervention fidelity assessment.

Specific Aim 2) Generate pilot feasibility data to inform the design of a RCT adequately powered to determine the efficacy of FACETS-TBI for improving fatigue outcomes in pwTBI. *Hypothesis 2a:* FACETS-TBI participants will report greater improvement in fatigue impact, fatigue severity, overall experience of fatigue, and self-efficacy of fatigue self-management than Attention Control participants, as measured by the Modified Fatigue Impact Scale, the Fatigue Symptom Severity Scale, and the PROMIS Fatigue Scale. *Hypothesis 2b:* The FACETS group will demonstrate an increase in frequency of participation in society compared to the Attention Control group as measured by the Participation Assessment and Recombined Tools-Objective. *Goal:* We will also qualitatively explore how participants perceive, understand, experience, and feel about FACETS-TBI through one-on-one interviews using the Narrative Evaluation of Intervention Interview (NEII).

Research Strategy

Design: We propose a randomized, parallel arm pilot study of FACETS-TBI compared to Attention Control.

Participants/recruitment: Potential participants are pwTBI who 1) participated in the Craig Hospital outpatient rehabilitation program in the past, 2) participate in the Peak Community Wellness Center, a wellness center at Craig Hospital designed for individuals in the community with neurological deficits, or 3) are Veterans with TBI who receive care in the VA Eastern Colorado Health Care System. Participants will be contacted via phone or email and those who are interested will be screened via phone or HIPAA-compliant teleconferencing software (e.g., Zoom, Teams) and will provide remote informed consent.

Inclusion criteria: (1) ≥ 6 months post-mild to severe TBI based on medical chart review of an initial Glasgow Coma Scale score ranging from 3 to 13, accompanied by neurological findings OR the Ohio State University TBI Identification Method (OSU TBI-ID); (2) Fatigue Severity Scale score ≥4; (3) community dwelling; (4) able to operate a computer (independently or assisted); (5) English fluency; (6) ≥18 years old; (7) capacity to self-consent; (8) no severe major depression; PHQ8 score ≤20

Sample Size. Based on a 7.3% attrition rate in a similar study targeting PTBIF conducted by Dr. Raina (ACAT member), we assume a 10% attrition rate and will therefore recruit 66 participants with a target retention of 60 participants (30 per treatment arm, randomized with equal probability). This sample size calculation is based on the feasibility of recruitment determined in our prior study. Craig Hospital admits ~170 patients with TBI into the outpatient program each calendar year and has a constituency of ~6,000 former patients with TBI, and in the past 12 months, over 2,000 Veterans with a TBI diagnosis received services through the VA Eastern Colorado Health Care System. We expect at least 50% to meet inclusion criteria and at least 40% of those to agree to participate. For hypotheses 1a and 1b, we expect metrics to be high in both groups and be similar between groups. While this feasibility study is not intended nor adequately powered to formally conduct non-inferiority or equivalence testing for hypotheses 1a and 1b, the estimates for these metrics from this study will be invaluable for designing a larger RCT with adequate power to further test these hypotheses. For Aim 2, we will collect pilot data associated with all hypotheses of interest in the larger RCT to assess the effect of FACETS-

TBI at improving fatigue outcomes. A sample size of 30 per group will allow us to assess the distributional assumptions of our outcome data (center, spread, normality, equal variability) and provide preliminary estimates (means and standard deviations) of change in outcomes over time for each group and differences in change between groups that can be used to assess the magnitude and direction of the effect size for each outcome. Power and sample size analyses indicates that a sample size of 30 per group has 80% power at a 5% level of significance to detect an effect size of at least 0.736 using a two-sample t-test, which is considered a large effect size. Sample sizes of at least 64 per group would be required to detect medium effects sizes (on the order of 0.5) as statistically significant, which will be the target of our future RCT.

Data Collection: Assessor will be blinded to group assignment. Time to complete ~45 minutes. See **Table 1.**

Measure	Description and Psychometric Properties	T1	Each Session	T2	T3
Demographics					
Demographics and TBI characteristics	Age, gender, race, ethnicity, education, time since injury, injury severity, comorbidities.	x			
Primary Outcomes for Aim 1					
Feasibility data *Aim 1, H1a*	Data collected at each scheduled session: Number of participants retained, duration of sessions, number of sessions completed/reason for non-completion.		x		
Participant Understanding *Aim 1, H1a*	Participant understanding will be rated by the interventionist ***after each session*** using a 3-point ordinal Scale (1=minimal, 2=some, 3=good). An independent rater will rate understanding for 20% of sessions to establish inter-rater reliability.		x		
Pittsburgh Rehabilitation Participation Scale *Aim 1, H1a*	PRPS is a validated and reliable scale that assesses effort and motivation during the intervention sessions (1=no engagement, 6=excellent engagement). Participation will be rated by the interventionist ***after each session***.[30] An independent rater will rate participation for 20% of sessions to establish inter-rater reliability.		x		
Client Satisfaction Questionnaire *Aim 1, H1b*	Validated measure satisfaction with health-related services that they have received.[31] 8 questions, each rated on a 4-point scale, yield a single summed score (ranging from 8 to 32) measuring overall satisfaction (higher scores indicate higher satisfaction).			x	
Fidelity Checklist *Aim 1, H1c*	The Fidelity Checklist will be developed by our ACAT in conjunction with the development of the Attention Control curriculum. It will include Adherence (Yes/No/NA) and Competence (High/Medium/Low/NA) and will be similar to the Fidelity Checklist that our team developed and published in the past.[32] We will implement Best Practices and Recommendations from the NIH Behavior Change Consortium—Enhancing Treatment Fidelity in Health Behavior Change Studies.[33] Fidelity will be assessed for a random 20% of sessions in each group.		x		
Primary Outcomes for Aim 2					
Modified Fatigue Impact Scale *Aim 2, H2a*	The mFIS has 21 items rated on a 5-point scale with scores ranging from 0-84 (higher scores=greater impact of fatigue on daily life), excellent internal consistency, good test-rest reliability, and a minimally important difference of 4.00.[34]	x		x	x
PROMIS Fatigue Scale 8a (experience of fatigue) *Aim 2, H2a*	The 8-item PROMIS Fatigue scale measures the experience of fatigue with a mean score of 50 (SD=10; higher scores indicate more fatigue) Recall: 7 days. It has a minimally important difference of .25 to .45[35]	x		x	x
Fatigue Symptom Severity (fatigue severity) *Aim 2, H2a*	The FSS consists of nine items, rated on a 7-point scale averaged for a total score ranging from 0-7 (higher scores indicate higher fatigue). It has excellent internal consistency and test-retest reliability and a minimally important difference of .45.[36]	x		x	x
Multiple Sclerosis-Fatigue Self Efficacy Scale (MS-FSE) *Aim 2, H2a*	We want to test whether FACETS-TBI will improve self-efficacy as it relates to fatigue. However, existing self-efficacy scales do not focus on fatigue, and therefore may not be specific enough to measure change in fatigue-related self-efficacy. We are aware of the Perceived Self-Efficacy for Fatigue Self-Management scale, but it has not been validated in the TBI population and does not include items related to a myriad of domains likely relevant to people with TBI fatigue (e.g., unpredictability and interference with everyday life). We have selected the MS-FSE, developed and validated in MS by Co-I Thomas.[37] While this measure is not currently validated in the TBI population, it is specific to fatigue-related self-efficacy and is not specific to MS alone. This measure will not require adaptation, as the content is not specific to MS.	x		x	x
Participation Assessment with Recombined Tools-Objective (PART-O) *Aim 2, H2b*	The PART-O demonstrates a person reliability of .86, item spread of 4.25 logits, item separation of 11.36, and item reliability of .99 and showed expected relationships with measures of impairment, activity limitations, and subjective well-being after TBI.[38]	x		x	x
NEII (interviews) *(Ai23, Goal)*	The Narrative Evaluation of Intervention Interview (NEII)[39,40] focuses on both the process and the outcomes of a psychosocial intervention. The interview is 16 open-ended questions designed to explore how participants perceive, understand, experience and feel about the intervention in which they participated.[41]			x	

Table 1: Study Outcomes. T1 (baseline): collected 1 week prior to session 1 of the intervention; each session: collected each FACETS-TBI session; T2 (Post intervention): collected on or within 1 week of final session; T3 (follow-up) collected 12 weeks from final session completion.

Procedure/intervention

Description of the FACETS intervention: The group-based remote intervention (no more than 8 participants) is six 60 to 90-minute weekly sessions designed to be delivered by a health professional (e.g., occupational therapists, nurses, physical therapists, speech therapists, psychologists). See **Table 2** for FACETS content. Participants are encouraged to bring a supportive other to the first session to foster lifestyle and attitudinal changes and to informally contact each other outside the group setting. Sessions transition from a practical approach to fatigue to a more psychological orientation, though cognitive behavioral components are introduced early in the intervention.

The facilitator manual (~100 pages) describes in detail the session content and provides preparation and delivery guidance, a checklist of session objectives, and links to additional resources. The intervention includes a participant handbook and informational booklets about fatigue and fatigue management that reinforces the FACETS content. Each session is structured in the same way, beginning with facilitator-delivered education and then transitioning to flipchart discussions, group activities, and homework. Sessions are delivered remotely via an online platform and can be easily replicated.[28]

Description of the Attention Control intervention: The Attention Control intervention is designed to control for the non-specific effects of FACETS-TBI (i.e., dose, attention, group format), and aligns with the current guiding principles for behavioral intervention Attention Control group development.[42] Attention Control sessions will be dose-matched to FACET-TBI sessions and use scripted open-ended questions about post-TBI healthy lifestyle-related topics (i.e., signs and symptoms of depression, memory and attention, cognitive problems, etc.) that promote reflection of lifestyle modification and related experiences. The Attention Control is derived from the Brain Health Group (BHG)[29], an attention control intervention previously validated in moderate to severe TBI. BHG is a 22 session, group-based educational support group for adults with TBI, theoretically grounded in Social Cognitive Theory and Health Beliefs model. The goal of BHG is to improve mental well-being and quality of life by increasing participants' knowledge of brain health. BHG has been delivered both in person and remotely. Our team has selected six of the 22 BHG sessions that do **not** address fatigue or sleep hygiene and do **not** use similar strategies that are found in the FACETS-TBI intervention, such as goal setting or planning. The Attention Control group will not receive any "active ingredient" components of FACETS-TBI. In lieu of FACETS-TBI homework, participants will complete the previously developed BHG homework assignments, reflections on thoughts and feelings about lifestyle modification after TBI.

Delivery of Intervention. Dr. Osborne (PI), an occupational therapist, will train and supervise two interventionists in the FACETS-TBI and Attention Control interventions. The interventionist will be trained using the adapted FACETS-TBI training manual and protocol developed by the ACAT team, which will also include the Attention Control intervention training and a fidelity assessment protocol. Participants will be scheduled for the FACETS-TBI or Attention Control sessions 1/week for an anticipated 6 weeks. The interventionists will conduct each weekly session and record feasibility and implementation data (see **Table 1)** to compare treatment fidelity and contamination of both interventions, following established protocols.[32]

Table 2. FACETS Intervention

	Session Content
1	General introduction; expectations; icebreaker (quiz); types of fatigue; contributing factors, conceptual model of fatigue in MS. **Homework: Activity/fatigue diary**
2	Rest – functions; barriers, techniques; relaxation types and techniques; diaphragmatic breathing; sleep hygiene. **Homework: Rest/activity/sleep planner**
3	Types of activity; balancing activity and rest; moderating activity using the toolbox; lifestyle factors; goal setting. **Homework: S.M.A.R.T. goal setting exercise**
4	The stress response (fight-or-flight); ways of coping with stress; introducing the cognitive behavioral model. **Homework: Unhelpful thoughts**
5	Unhelpful thought patterns; challenging unhelpful thoughts; levels of belief. **Homework: Thought challenge sheet**
6	Revisiting expectations; introducing the 'forcefield'; group activity to revisit themes of the program; rationale of 'Keeping on Track' planner. **Homework: 'Keeping on Track' planner**

Semi-structured interviews. All enrollees assigned to the FACETS-TBI group will participate in a semi-structured one-on-one interview (NEII) upon completion of the intervention to provide an understanding of participants' experience of FACETS-TBI and to elicit their recommendations regarding the intervention design and content. The interviews will last approximately 1 hour and will be conducted by Dr. Osborne (PI).

Potential Problem Areas & Alternative Methods and Approaches

- Recruitment. Though we have demonstrated previous success recruiting for studies of community-dwelling adults with TBI, unforeseen problems may occur in recruiting study participants, particularly those from minoritized or marginalized groups. In the unlikely event that this occurs, we will leverage the expertise and networks of our ACAT to adapt and expand our recruitment approach.
- Retention and missing data. Participants may withdraw or miss sessions; though not preferred, understanding how often this happens and why it happens will be critical information for future translation. Problems may arise with missing data. We have extensive experience conducting follow-up interviews via phone, mail, internet, and in combination, having established effective methods to ensure complete data collection. However, in the unlikely event that we have missing data (>10%), we will attempt to over-sample to ensure sufficient complete data for analyses. We will assess differences in those with and without complete data.

Statistical and Data Analysis Plan. Data management will be implemented with a secure database that is password protected and HIPPA compliant. It is capable of sending participant surveys, facilitates a variety of quality control procedures, and generate queries when potential errors or missing data are detected. Descriptive statistics including means, standard deviations, percentiles, frequency counts, and proportions will be used to summarize participant characteristics within each treatment arm. Chi-square tests and two-sample t-tests will be used to compare baseline characteristics between groups at a significance level of 0.05. **Aim 1**: The proportion of participants retained immediately post intervention and at 12 weeks follow-up, total session duration, proportion of sessions completed, PRPS (level of engagement), Participant Understanding, and CSQ (acceptability) scores will be summarized for each group along with 95% confidence intervals and these metrics compared using chi-square tests and two-sample t-tests; non-parametric alternatives will be used as appropriate. In lieu of formal equivalence testing which requires substantially larger sample sizes than this feasibility study is designed for, we will assess and report on the magnitude of the difference between group means and proportions on each of these metrics. **Aim 2:** Scores for the Modified Fatigue Impact Scale, PROMIS Fatigue Scale, Fatigue Symptom Severity Scale, perceived self-efficacy (MS-FSE), and participation (PART-O) will be summarized by group at each time point (baseline, post-intervention, 12 weeks follow-up) along with changes in outcomes over time (baseline to post-intervention and baseline to 12 weeks follow-up). Distributional assumptions for each outcome will be assessed including normality and heterogeneity of variance. ANCOVA models will be used to estimate the effect size for each outcome. For each outcome variable, the ANCOVA model will use the change score (baseline to post, or baseline to follow-up) as the outcome, and include main effects for group and baseline score. The effect size and associated 95% confidence intervals will be estimated from this model and is quantified as the estimated difference in outcome change scores between groups, adjusted for baseline scores. A power and sample size analyses indicates that a sample size of 30 per group has 80% power at a 5% level of significance to detect an effect size of at least 0.736 using a two-sample t-test, which is considered a large effect size; however, medium effect sizes (on the order of 0.5) will be assessed for further exploration in a larger RCT as these are still clinically meaningful. To address the Aim 2 *goal*, we will conduct one-on-one interviews. All interviews will be audio recorded and field notes will be documented during the interviews. All audio-recordings will be transcribed verbatim using Otter.ai, a real-time automatic transcription service with Zoom-linking capabilities. Content analysis of each transcript and document will be conducted by two separate coders. Any coding discrepancies will be resolved through discussion. Coded concepts will be merged and categorized by theme in Atlas.ti Version 23. Matrices will be used to organize the themes and identify emerging patterns of subthemes (relevant and frequently addressed topics related to each main theme).[43] To contribute to the internal validity of the process, investigator triangulation will be used to decrease potential biases in gathering, coding, and reporting the data.[44-46] The result of the content analysis will generate codes identifying aspects of FACETS-TBI to keep, add, or modify.[47]

Protection of Human Subjects

Below is the detailed information needed to address protection of human participants in the proposed study. All human participant research will be conducted at Craig Hospital and the Rocky Mountain Veterans Affairs Medical Center (RMVAMC). We will recruit participants from both Craig Hospital and the Eastern Colorado Veterans Affairs (VA) Healthcare System, of which the RMVAMC is a part. The Eastern Colorado VA Healthcare System is comprised of the RMVAMC (main medical center) and 13 satellite VA clinics. The WCG

IRB will provide oversight and IRB approval, as the IRB of record for Craig Hospital. Approval will be obtained prior to participant enrollment.

Study Population

We will enroll n=66 participants in this pilot feasibility study of **FACETS-TBI** for adults with Post Traumatic Brain Injury Fatigue (PTBIF) to: (1) establish an attention-control protocol for use in this study as well as a future randomized control trial and (2) measure participant response to and engagement in both FACETS-TBI and Attention Control groups to determine the effects of FACETS-TBI on fatigue beyond either the passage of time or the non-specific effects that could occur in a control intervention. (n~33 participants per site). Both recruiting sites and site investigators have a strong track record of recruiting individuals with brain injury. Craig Hospital is currently a NIDILRR-funded TBI Model Systems, enrolling a minimum of 35 patients per year with moderate to severe TBI who are then followed at 1-year, 2-years, 5-years, and every subsequent 5-years after injury. Craig has been funded for several cycles, currently following over 1000 participants each Approximately 13% of the TBI Model Systems participants have a history of military service. In the past 12 months, over 2,000 Veterans with a TBI diagnosis, across severity type, received services through the Eastern Colorado VA Healthcare System.

Inclusion/Exclusion Criteria

Inclusion criteria	***Rationale***
1) ≥ 6 months post mild to severe TBI	TBI severity based on medical chart review of an initial Glasgow Coma Scale score and accompanied by neurological findings OR the Ohio State University TBI Identification Method (OSU TBI-ID)
2) English fluency	FACETS-TBI will be developed initially in English
3) Capacity to self-consent	Cognitively able to make independent decisions and actively engage in Cognitive Behavioral intervention.
4) Access to the internet and able to operate a computer (independently or assisted)	FACETS can be delivered in-person, remotely or as a hybrid. Based on prior FACETS feedback and barriers to access, we anticipate that the ACAT team may recommend a remote or hybrid approach.
5) Fatigue Severity Scale score ≥ 4	Participants must demonstrate clinically significant trait level fatigue to benefit from the fatigue management intervention
Exclusion criteria	***Rationale***
1) Self-reported history of neurodegenerative condition or schizophrenia	The ability to benefit from a CBT intervention may be affected by these conditions and should be examined separately.
2) no severe depression; PHQ8 score ≤ 10	Severe depression can impact one's ability to actively engage in a CBT self-management program.

Protection of vulnerable populations

Individuals who do not have the capacity to self-consent will be excluded from the project. This decision will be made by the research coordinator consenting the participant and will be based on the participant's ability to actively engage in the informed consent process and answer relevant questions that demonstrate understanding of the study. Each potential study participant will be asked to state in his/her own words what the purpose of the study is, what he/she is expected to do, and what the risks and benefits are. Based on their responses, the individual obtaining informed consent will assess the individual's capacity to comprehend the project and his/her ability to provide informed consent. If it is determined that the individual has diminished mental capacity to provide informed consent, consent will not be obtained, and the individual will be excluded from the study.

Recruitment Process

We will recruit n=66 persons with TBI, across the range of injury severity and time since injury and including both civilians and Service members from Craig Hospital and the Eastern Colorado VA Healthcare System. Research coordinators at Craig and the RMVAMC will identify potential participants through a combination of physician referral from outpatient clinics and other post-acute services, association Craig Hospital's TBI Model Systems study, past participation in other ABI-related research, site-specific research registries, or response to shared study flyers (electronic via email lists and social media and paper flyers). Flyers will not include any coercive language or offer undue inducements; participants will be compensated $25 (assessment 1), $30 (assessment 2), $35 (assessment 3), and $35 (focus group participation), (up to $125 if they complete assessments at all time points). Potential participants will be approached by the research coordinator and presented with the opportunity to enroll in the study, provided with information about the nature and purpose of the research, and offered answers and explanations to all their questions and concerns. All consenting will take place through either Craig Hospital or RMVAMC. RMVAMC participants will be referred to a study coordinator at Craig Hospital after consenting for additional screening to confirm eligibility.

Informed Consent Process

Consent will be at a language level that is easily understood by most individuals with at least a 6th grade education and each participant will have an information sheet to follow to ensure they understand study procedures. All participants will be informed of the full purpose of the study. Time and effort commitments required for study participation will be explained. Verbal feedback will be solicited from potential participants about their understanding of the study, its risks, and potential benefits prior to completion of the informed consent form. Each potential study participant will be asked to state in their own words what the purpose of the study is, what they are expected to do, and what the risks and benefits are. Based on their responses, the individual obtaining informed consent will assess the individual's capacity to comprehend the project and their ability to provide informed consent. If it is determined that the individual has diminished mental capacity to provide informed consent, consent will not be obtained, and the individual will be excluded from the study per exclusion criteria. All potential participants will be given access to a PDF copy of the consent form. Prior to providing consent, all potential participants will be given the opportunity to review the consent document, discuss it with whomever they choose (including the study investigators), and take as much time as they need to consider the information that has been presented to them to make an informed decision. The research coordinators, principal investigators, and co-investigators at each site will be available to the participants to clarify information and answer any questions. Participants will be given as much time and privacy as they request while deciding whether to enroll (or remain enrolled) in the study. No personal health information will be recorded until obtaining informed consent. Informed consent will be obtained from all enrolled participants in accordance with Institutional Review Board (IRB) policies. Potential participants will be informed that there is no penalty for refusal to participate. The research coordinator will be responsible for explaining the study, answering questions, and obtaining informed consent. Consent documents will be maintained within a secure database that is password protected and HIPPA compliant. The consent process will occur via telephone or video conference.

Screening Procedures

The research coordinator will be responsible for confirming study criteria requirements. A waiver of consent will be requested to complete initial screening, which will include the Fatigue Severity Scale, English fluency, access to the internet/able to operate a computer with or without assistance, Patient Health Questionnaire-8, and history of neurodegeneration condition. The coordinator will confirm capacity to consent during the consent process.

Risks/Benefits Assessment

Foreseeable risks

The proposed studies involve minimal risk to participants. There is always a risk of a breach of confidentiality of personal information and associated privacy of participants. The baseline screening, FACET-TBI sessions, and follow up data collection procedures may produce discomfort or anxiety secondary to the discussion of

emotionally-laden topics. All interventionists will be experienced clinicians with prior experience working with individuals with TBI and handling sensitive topics. Some of the questions asked or prompts provided may be on topics that are sensitive and cause embarrassment. Study participants may refuse to answer these questions.

Risk management and emergency response

Risks resulting from this study are expected to be minimal. To assure participant confidentiality and privacy, all participants will be assigned a unique study identification number. All identifiers will be coded as such in a secure database with user-access restricted only to those approved through access identifiers. Subject IDs will be used during all statistical analysis. Consent forms and all study documents will be maintained by the PI and Co-investigators at participating centers on cloud-based secure servers. All remote communication will take place on Zoom or Teams, both are HIPAA compliant web and video conferencing platform.

Every effort will be made to minimize feelings of stress, discouragement, and distress in participants. To minimize psychological discomfort, the PI and Co-I's will train the research coordinators administering questionnaires in empathic listening and interviewing skills. Basic principles to be discussed during these trainings include gradual pacing of interviews and allowing participants to return to or defer items that are the source of distress. The interventionists will be graduate-trained clinicians with experience working with patients with TBI, so will be equipped with the skills for minimizing and managing psychological discomfort. Emergency protocols have been established at both sites for managing crises (e.g., a participant endorsing suicidal thoughts during the intervention session), with appropriate oversight from qualified study investigators. A licensed Psychologist (Dr. Holliday) on the study team will be available for crisis management as needed. Furthermore, participants will be informed that they have the option to withdraw from the project at any time.

Potential benefits

Participants may benefit from the FACETS-TBI intervention through improved self-management skills. From this study, we hope to improve available supportive interventions for TBI survivors living in the community. Evidence supporting usability and engagement with FACETS-TBI could have relevance for multiple clinical populations, particularly those with cognitive deficits. The proposed study has the potential to make a significant contribution to the field by supporting an evidence-based, self-management intervention that promotes adaptive coping and fatigue-self efficacy among TBI survivors who experience chronic fatigue. For these reasons, the investigators believe that the benefits of the investigation outweigh the very minimal risks involved.

Data Management

Identifiers

To assure participant confidentiality and privacy, all participants will be assigned a unique study identification number. All identifiers will be coded as such in HIPAA compliant database on the Craig Hospital server with user-access restricted only to those approved to access identifiers. Subject IDs will be used during all statistical analysis.

Confidentiality

Data will be collected directly from participants on study forms in an electronic database that meets standards required for HIPAA-compliance and participating sites' IRBs. Participants will be assigned a unique study identification number. All identifiers will be coded as such in secure database with user-access restricted only to those approved to access identifiers. Consent forms and all study documents will be maintained by the PI and Co-investigators at participating centers on cloud-based secure servers.

Only the PI, Co-investigators, and members of the research team (e.g., clinical research coordinators, interventionists) will have access to any personal identifiers. As appropriate for audit or other regulatory purposes, authorized representatives from the WCG IRB may be granted access to the data for monitoring the conduct of the study. The data collected will not be used to reidentify individuals and no personally identifiable information will be disseminated or analyzed. All participants will be given a unique subject ID, and all identifiers will be coded as such in secure database. Subject IDs will be used during statistical analysis. All staff will be trained regarding the confidentiality involved with the study as per institutional protocols for

maintaining Human Subjects Research training. All participants will be made aware that their private information will remain confidential and what entities will have access to their information.

In addition to the measures noted above regarding protection of personal identifiers, access to all study data will be limited to the study team. Participants will be informed prior to any data collection that representatives from Craig Hospital and from the DoD are eligible to review study records. Though some questions assess sensitive topics, we will not collect any data that would fall under the umbrella of mandatory reporting or that would assess immediate crisis (e.g., suicidal ideation).

Data capture, verification, and disposition

All data are captured and stored for 7 years via an electronic survey. Service member status will be verified through questions about pay grade, rank, and subspecialty specific occupational code (either current or at discharge). Data will be collected directly from participants on study forms in an electronic database that meets standards required for HIPAA-compliance and participating sites' IRBs. All electronic data will be stored in a secure database, with user-controlled access. The database will be developed by the technology team at Craig Hospital, the technology team at Craig has ample experience in both data storage and direct data capture. A web-based data entry system is attached to a Microsoft SQL server. The software allows for dynamic reporting and monitoring of data, as well as providing real-time data error and/or consistency checks to ensure quality data. The databases will utilize whole database encryption via a third-party software called Encryptionizer which encrypts the database and backups using FIPS 140-2 standard which is common for encryption of sensitive data. Access to the data will be maintained through Identity Server 4, which will handle both authentication and authorization to the web site and data. The database and all project files will be backed-up regularly on a schedule determined by Craig's IT department, which allows for quick retrieval of daily, weekly, or monthly backups. The architecture of the network infrastructure maintains intrusion detection systems and robust firewalls to filter traffic throughout the network.

At completion of the study, participants will complete a short semi-structured interview about their experience in the intervention. Interviews will be audio-recorded, transcribed verbatim, and de-identified prior to analysis. All audio files and transcripts will be saved behind Craig Hospital's firewall on secure cloud-based system with user-access restrictions.

Data reporting

Data will be reported via aggregated summaries and statistical comparisons, addressing the proposed specific aims. Statistical analysis addressing additional research questions may also be conducted on de-identified data, and de-identified data may be shared via established protocols described in the Sharing of Data and Resources Plan (in Support.pdf document). Regulatory filing with the FDA is not required for the proposed studies.

Sharing study results

We are not performing any diagnostic tests or screening for medical conditions as part of these studies; therefore, there would be no instance in which we would have relevant information to share with participants or their primary care providers. We have outlined a dissemination of research findings plan (see Support.pdf document and Transition.pdf document), to make the aggregated results and products available to the public, participants, and healthcare providers.

Laboratory Evaluations

Not applicable to this proposal.

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